



What is the BTOD REMS?

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) for Buprenorphine-containing Transmucosal products for Opioid Dependence (BTOD). A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure that the benefits of a drug outweigh its risks.

The purpose of the BTOD REMS program is to inform healthcare professionals and patients about the safe use conditions and serious risks, including accidental overdose, misuse, and abuse, associated with buprenorphine-containing transmucosal products indicated for the treatment of opioid dependence.

What products are covered under the BTOD REMS?

Buprenorphine-containing products are available both as products containing buprenorphine only, and products that combine buprenorphine with naloxone; both types of products are indicated for the treatment of opioid dependence.

The drug products subject to the Buprenorphine-containing Transmucosal products for Opioid Dependence (BTOD) REMS include:

- Generic equivalents of Subutex® (buprenorphine) sublingual tablets
- Generic equivalents of Suboxone® (buprenorphine and naloxone) sublingual tablets and sublingual films
- Zubsolv® (buprenorphine and naloxone) sublingual tablets
- Bunavail® (buprenorphine and naloxone) buccal films
- Cassipa® (buprenorphine and naloxone) sublingual films

The use of buprenorphine-containing products should be part of a comprehensive treatment plan to include counseling and psychosocial support. Treatment must be initiated under the direction of prescribers qualified under the Drug Addiction Treatment Act of 2000.

Where can I obtain additional information?

Please see the [Prescribing Information](#) and [Medication Guide](#) for all buprenorphine-containing products.

For more information about the BTOD REMS, including all program materials and instructions call **1-855-223-3922**.

General information about buprenorphine treatment and the treatment of addiction are available through numerous sources, including but not limited to:

- SAMHSA website (<https://www.samhsa.gov/medication-assisted-treatment>)
- American Society of Addiction Medicine website (www.asam.org)
- American Academy of Addiction Psychiatry website (www.aaap.org)

To report SUSPECTED ADVERSE EVENTS, contact:

- The manufacturer of the product taken or
- FDA MedWatch program by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm

To prescribe products covered under the BTOD REMS, a prescriber must be certified to treat opioid dependence under the Drug Addiction Treatment Act of 2000 (DATA 2000). For certification information, [click here](#).

[Click here for a complete list of products covered under the BTOD REMS program](#)

Materials for Prescribers:

- [Dear Prescriber Letter](#)
- [Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers](#)
- [Appropriate Use Checklist](#)

Materials for Pharmacists:

- [Dear Pharmacist Letter](#)
- [Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists](#)

Materials for Patients:

- [Medication Guides](#)

For more information or to receive print copies of the materials, please call:
1-855-223-3922.

This REMS does not apply to buprenorphine-containing products indicated for the treatment of pain or for products dispensed to patients admitted to Opioid Treatment Programs (OTP) under 42 CFR part 8.

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Prescribers play an important role in reducing the risks of accidental overdose, misuse, and abuse, associated with buprenorphine-containing transmucosal products. To help mitigate these risks, prescribers should:

- **Verify** the patient meets appropriate diagnostic criteria for opioid dependence.
- **Check** patient's prescription profile in the Prescription Drug Monitoring Program, as appropriate, and review all medications (e.g., benzodiazepines, other opioids, CNS depressants) and illicit substances to assess for appropriateness of co-prescribing.
- **Discuss the risks** (including misuse and abuse) **and side effects** associated with buprenorphine-containing products, including those described in the Medication Guide. (See the brochure, [Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers](#) for additional safety information regarding these risks.)
- **Explain** what patients should do if they experience side effects.
- **Provide induction** doses under appropriate supervision.
- **Prescribe a limited amount** of medication to the patient that will last until the next visit.
- **Explain** how to store the medication safely **out of sight and reach of all others, especially children**.
- **Schedule** patient appointments commensurate with patient stability (weekly or more frequent visits recommended for the first month).
- **Consider** "pill/film count"/dose reconciliation.
- **Assess** whether the patient is receiving counseling/psychosocial support considered necessary for treatment and if not, encourage them to do so.
- **Assess** whether the patient is making progress toward treatment goals (including, as appropriate, urine toxicology testing).
- **Continually assess** appropriateness of maintenance dose.
- **Continually assess** whether or not benefits of treatment outweigh the risks.

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Pharmacists play an important role in reducing the risks of accidental overdose, misuse, and abuse, associated with buprenorphine-containing transmucosal products. To help mitigate these risks, pharmacists should:

- **Verify** that the prescription you receive is from a prescriber who is in compliance with the provisions of DATA 2000.
- **Check** patient's prescription profile in the Prescription Drug Monitoring Program, as appropriate, and review all medications (e.g., benzodiazepines, other opioids, CNS depressants) to assess for appropriateness of co-prescribing.
- Keep in mind that a **limited supply of buprenorphine-containing products should be dispensed** during the initiation of therapy. This is due to the need of prescribers to closely and frequently assess the patients' needs, their symptoms, and potential risk of misuse, diversion, and abuse.
- **Provide** the Medication Guide to patients each time the medicine is dispensed and discuss the risks and side effects associated with buprenorphine products, including what to do if patients experience side effects.
- **Remind** patients who are picking up induction doses to return as directed to the prescriber's office so that they can be supervised while taking the medication.
- **Explain** how to store the medication safely out of sight and reach of all others, especially children.
- **Provide** appropriate patient counseling on safe use of buprenorphine-containing products and encourage patients to seek psychosocial counseling and support for safe and effective treatment.
- **Be vigilant** in detecting fraudulent prescriptions or simultaneous prescriptions for the same patient from multiple prescribers.
- **Review** the brochure [Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists](#) for additional information.

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Patient Education is a critical component of treating patients with buprenorphine products. The respective Medication Guides for each of the buprenorphine products contain important information about the product, including proper administration, potential adverse events, and other precautions. You should review the medication guide with patients for whom you prescribe each buprenorphine product to ensure that they understand the proper use and safety precautions associated with these products.

Communicate the following **messages** to patients about the **risks of accidental overdose, misuse, and abuse**:

- **Instruct patients to keep these products in a secure place, out of the sight and reach of all others, especially children. Accidental or deliberate ingestion by a child may cause respiratory depression that can result in death. Advise patients to seek medical attention immediately if a child is exposed to one of these products.**
- Warn patients that it is extremely dangerous to self-administer non-prescribed benzodiazepines or other central nervous system (CNS) depressants (including alcohol) while taking these products. Caution patients prescribed benzodiazepines or other CNS depressants to use them only as directed by their prescriber.
- Advise patients never to give these products to anyone else, even if he or she has the same signs and symptoms. They may cause harm or death.
- Advise patients that these products contain an opioid that can be a target for people who abuse prescription medications or street drugs. Caution patients to keep their products in a secure and safe place, out of the sight and reach of all others, especially children, and to protect them from theft.
- Advise patients that selling or giving away these products is against the law.
- Use the contents of each BTOD drug product's Medication Guide, in its entirety, with each patient to review the information noted above, including side effects and what to do if a patient has them. The Medication Guide will be dispensed with each prescription for a buprenorphine-containing transmucosal product.
- **Strongly encourage patients to seek psychosocial counseling and support for safe and effective treatment.**

Additional information for prescribers about safe use conditions and patient monitoring can be found in the [Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers](#) and the Warnings and Precautions sections of the product-specific Prescribing Information.

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/s/

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